K014081
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MAR 5 2002

Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act

May 1, 2001

1. General Provisions

Trade Name: Radiation Therapy Wedges
Common Name: Beam Modifier, Wedges

Applicant Name and Address: AKTINA Medical Physics Corporation
360 North Route 9 W
Congers, New York, 10920
Phone: 914-268-0101
FAX: 914-268-1700
Registration Number: 2436865

2. Name of Predicate Devices

Mevatron KD-2, Siemens Medical Labs, Inc., K862339

Clinac 1800, Varian Associates, Inc., K832503 1

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seg. (1977).

3. Classification

This device is classified as a class II device according to 21 CFR 892.5770.

4. Performance Standards

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product.

5. Intended Use and Device Description

The AKTINA Medical Physics Corporation ABC System is intended for use in Radiation Therapy as beam modifying agent. It is only for use in external beam radiation therapy with photon beams.

6. Biocompatibility

This product raises no issues of biocompatibility.

7. Summary of Substantial Equivalence

This device is similar in design and intended use and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2002

Ms. Joan Zacharopoulos
Vice President
AKTINA Medical Physics Corp.
360 North Route 9W
CONGERS NY 10920

Re: K014081
Trade/Device Name: AKTINA Medical Physics Corporation Radiation Therapy Wedges
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: November 1, 2001
Received: December 11, 2001

Dear Ms. Zacharopoulos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K014081

Device Name: Radiation Therapy Wedges

Indications for Use:

In radiation therapy, it is often desirable to modify the intensity or penetrating depth of a treatment beam so as to minimize radiation exposure to normal tissue. Many devices have and are used for this function including but not limited to partial beam blocks, tissue compensating filters, the most commonly, the wedge. This physical device is constructed of high-density materials that when machined into a wedge shaped block, differentially attenuate the transmitted radiation beam. The resulting radiation beam that is transmitted through the wedge will have a sloped intensity at the patient surface as compared to an un-attenuated beam, which is uniform and consistent in intensity across the beam at the patient's surface. These wedges are designed for use only as a beam-modifying agent with photon beams in Radiation Therapy external beam treatments.

David C. Seymour

Sign-Off
Reproductive, Abdominal,
ogical Devices
umber K014081

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: √ or Over-The Counter Use: (Per 21 CFR 801.109)